

K121689

SEP 19 2012

510(K) Summary

This summary is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1) Submitter's name, address, telephone number, contact person:

Ron Evans
VP Product Development
Vitacon Medical Inc.
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Date Prepared: May 10, 2012

2) Name of the Device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/Usual Name:	Bladder Scanner
Proprietary Name:	VitaScan LT, and Scanmaster
Classification Name:	Ultrasonic Pulsed Echo Imaging System (892.1560; 90-IYO) Diagnostic Ultrasound Transducer (892.1570; 90-ITX)

3) Identification of the predicate or legally marketed device:

Vitacon Medical Inc. believes this product is similar in design and function to the Life-Tech Inc. Vesiscan (K093485) and the Diagnostic Ultrasound Corporation BladderScan™ BVI 6100 (K022153), and BladderScan™ BVI 9400 (K071217) which are legally marketed post-amendment devices.

4) Device Description:

The VitaScan LT (aka. Scanmaster) is a hand held, B mode ultrasound scanner with a USB interface to a personal computer. This software controlled ultrasound system is used to acquire and display representations of the bladder, from which the bladder volume can be calculated. The system is intended to non-invasively monitor bladder volume on an intermittent basis which may be used to assist in the determination of time for bladder emptying and for the detection of post void residual volume (PVR).

The VitaScan LT (aka. Scanmaster) is a Track 1 System and meets the FDA's pre-amendment acoustic output limits for "fetal imaging and other" applications.

5) Intended Use:

The VitaScan LT (aka. Scanmaster) is a B-mode ultrasonic instrument which projects ultrasound energy through the lower abdomen of the non-pregnant patient to obtain an image of the bladder which is used to determine bladder volume non-invasively, on an intermittent basis. Bladder scanning measures ultrasonic reflections within a patient's body and differentiates the urinary bladder from the surrounding tissues. The intended use of the device, as defined by FDA guidance documents, is for Abdominal (adult and pediatric) applications.

VitaScan LT is applicable in many clinical areas to determine bladder volume, time for bladder emptying and detection of post void residual volume (PVR).

6) Technological Characteristics:

The VitaScan LT (aka. Scanmaster) is a 2.3 MHz mechanical sector scanner which operates only in the B mode to locate the bladder and automatically calculate the bladder volume. The ultrasonic power transmitted by the system is not user adjustable. Bladder Volume, Patient ID, Patient Name, Gender, Age and Hospital Name are displayed and stored on the personal computer application program provided with the VitaScan LT (aka. Scanmaster), which is connected to, and receives power through, the USB port of the personal computer.

VitaScan LT (aka. Scanmaster) is applied to the patient's abdomen, immediately superior to the patient's symphysis pubis with an ultrasound gel interface. The transducer collects cross-sectional images of the bladder from up to 24 scan planes and transmits the image information to the personal computer via the USB connection. Using this information, the VitaScan LT application program constructs a finite element model of the bladder and automatically computers the volume of the bladder via volumetric integration.

For confirmation of operation and accuracy, the user may scan a known volume contained within an optional phantom.

7) Technical Comparison to Predicate Devices:

The VitaScan LT (aka. Scanmaster) is substantially equivalent to the currently marketed Vesiscan, and the BladderScan™ BVI 6100 and BVI9400, referenced previously. All devices are pulsed echo ultrasonic imaging instruments dedicated to non-invasive measurement of urinary bladder volume. Although there are some technological differences between the devices, such as frequency of operation and acoustic output, these differences are minor and raise no new questions of safety and effectiveness.

8) Performance Data:

Non-clinical testing included acoustic output testing; thermal, mechanical and electrical safety testing; electromagnetic emissions and immunity testing; biocompatibility testing; and, testing with a physiological phantom of a urine filled bladder. All non-clinical testing demonstrated the subject device to be substantially equivalent to the predicate devices in terms of safety, effectiveness and performance.

Clinical testing of the subject device was performed on healthy volunteers. No adverse effects or complications were noted, and the results demonstrated that the subject device is substantially equivalent to the predicate devices in terms of safety and effectiveness.

9) Conclusion:

All testing demonstrated the VitaScan LT (aka. Scanmaster) is as safe, as effective, and performs as well as the legally marketed predicate devices. The VitaScan LT (aka. Scanmaster) is substantially equivalent to the currently marketed Vesiscan and BladderScan™ BVI 6100 and BVI 9400 with respect to intended use, technological characteristics, and performance.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Ron Evans
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CANADA

SEP 19 2012

Re: K121689
Trade/Device Name: VitaScan LT (a.k.a. Scanmaster)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: July 26, 2012
Received: July 27, 2012

Dear Mr. Evans:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

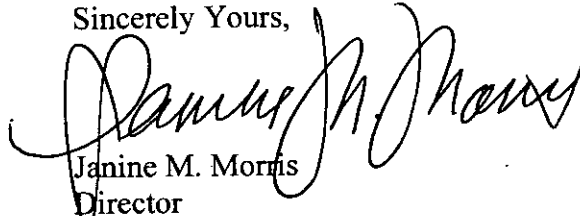
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name.


Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications For Use

The VitaScan LT (aka. Scanmaster) is a B-mode ultrasonic instrument which projects ultrasound energy through the lower abdomen of the non-pregnant patient to obtain an image of the bladder which is used to determine bladder volume non-invasively, on an intermittent basis.

Prescription Use X
Part 21 CFR801 Subpart D


(Division Sign-Off)
Division of Radiological Devices
DIVD
\$10K K121689

Diagnostic Ultrasound Indications For Use


System: VitaScan LT (aka. Scanmaster)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body, as follows:

Clinical Application		Mode of Operation						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Opthalmic	Opthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P						
	Inter-operative (Specify)							
	Inter-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (Non-Card)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other(Specify)							
Peripheral Vessel	Peripheral Vessel							
	Other (Specify)							

P = Previously cleared by FDA (K022153, K071217)

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Radiological Devices
 510k K121689